DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 4, 2015

KaVo do Brasil Industria e Comercio Ltda
Mr. Marcos Fernandes Nunes
RA/QA Manager
Rua Chapeco, 86
Joinville, Santa Catarina 89.221-040
BRAZIL

Re: K141576
Trade/Device Name: Maxima PRO 45L
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: March 23, 2015
Received: April 3, 2015

Dear Mr. Nunes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section IV - Indications for Use

510(k) Number (if known): K141576

Device Name: ***Maxima PRO 45L***

Indications for Use:

This air-powered dental handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.
It is designed for use by a trained professional in the field of general dentistry.

Prescription Use ___X____ Use _____ (Part 21 CFR 801 Subpart D)	AND / OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141576

Device Name
Maxima PRO 45L

Indications for Use *(Describe)*
This air-powered dental handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.
It is designed for use by a trained professional in the field of general dentistry.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K141576

Section V - 510(k) Summary

Submitter:

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Rua Chapecó 86
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Marcos Fernades Nunes - Contact Person
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Date of Summary: April 30, 2015

Device Name:

- Trade Name - ***Maxima PRO 45L***
- Common Name - Handpiece, air-powered, dental
- Classification Name - Dental Handpiece and accessories, per 21 CFR § 872.4200
- Product Code and Classification – EFB, Class I

Devices for Which Substantial Equivalence is Claimed:

- HIGH SPEED AIR TURBINE HANDPIECES TI Max X 450 (K112024) marketed by Nakanishi, Incorporated
- HIGH SPEED AIR TURBINE HANDPIECES Karan 45, Dexor 45 (K101717) marketed by Aerobine, Incorporated

Device Description:

The Maxima PRO 45L air-driven handpieces are air driven dental handpieces for the use by a trained professional in the field of general dentistry. The devices are air-powered handpieces that are reusable and ergonomically shaped. The devices can be sterilized by the gravity steam autoclave methods that have been validated. Through the coupling connected to a dental unit, the proposed dental handpiece receive air for functionality of the high speed turbine. They also receive cooling water for cutting through one port and light for illumination through another port.

Further one there is a jet needle supplied with the Maxima PRO 45L. By using this part the operator is able to clean the spray port in the head of the product if there is an insufficient amount of cooling water out of the Maxima PRO 45L according to the instructions for use.

The mechanism of action for the proposed air driven handpieces is as follows:
The dental handpieces is an air-driven handpiece which will be supplied with water, air and light through the tube and the coupling of a dental treatment unit.
The handpiece is operated by pneumatic pressure applied on the cartridge, providing a rotation between 380,000 and 420,000 rpm.

For proper operation, set air pressure on the dental treatment unit at 40 ± 1.45 psi and check with a pressure gauge Air supply must be dry, clean, and uncontaminated.
For the cooling water, a minimum of 50 ml/min (pressure 14.5 ± 1.5 psi (1± 0.1) of water is needed.
The Multiflex coupling has a bulb which enables thought existing optical fiber in the handpiece, the lighting at the place of action of the drill.
Dental burs (not part of this 510(k)) according to ISO 1797-1 type 3 could be inserted into the chuck system of the turbine. The Maxima PRO 45L interacts with the patient through a rotating bur with the patient teeth according to the intended use.
The Maxima PRO 45L is providing with connection MULTIflex system. The connectors carry the air for the high speed turbine, the cooling water for cutting treatment and light for illumination from the dental treatment unit.
The coupling is an accessory that permits quick exchange of the work equipment and high cost-effectiveness when extending your range of instruments. As a matter of course each dental instrument can be ergonomically rotated 360° on the MULTIflex coupling.
The MULTIflex connectors are accessories to the medical device which will not be delivered together with the Maxima PRO 45L.

Indication for use:

This air-powered dental handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.
It is designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The proposed air driven handpieces functions in a manner similar to, and are intended for the same use as the TI Max X 450 (K112024) marketed by Nakanishi, Incorporated and to the Karan 45, Dexor 45 (K101717) marketed by Aerobine, Incorporated.
The proposed handpieces are similar to the two predicate devices in that they are dental air-driven handpieces for use by a trained professional in the field of general dentistry. Proposed handpieces are substantially equivalent in design, indication for use and function to the two predicate devices noted above. The proposed handpieces and the predicate devices are reusable (sterilizable) and ergonomically shaped. Both the proposed device and the predicate devices receive air for the high speed turbines to function, and the cooling water for cutting treatment through the tube and the specific coupling of a dental unit.
For proper operation, set air pressure on the dental treatment unit at 40 ± 1.45 psi and check with a pressure gauge Air supply must be dry, clean, and uncontaminated.
For the cooling water, a minimum of 50 ml/min (pressure 14.5 ± 1.5 psi (1± 0.1) of water is needed.

The proposed handpieces differs from the TI Max X 450 (K112024) and to the Karan 45, Dexor 45 (K101717), in the head size dimension and the compliance to standards. The proposed device have been evaluated according to the new standard ISO 14457:2012 - Dentistry Handpieces and Motors, and the predicate devices have been evaluated according to the older version of ISO 7785-1:1997 – Dental Handpieces – Part 1 High –Speed air turbine Handpieces.

The performance test demonstrates that the differences in technological characteristics between the proposed handpiece and the predicate handpiece do not raise additional questions. The testing has been performed using the updated standard that was used in the predicates device.

Summary of the Technological Characteristics:

Descriptive Information	***Maxima PRO 45L***	Primary Pred. K112024	Reference Device K101717
Indications for Use	This air-powered dental handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures. It is designed for use by a trained professional in the field of general dentistry.	The Ti-Max X450 is an air-powered dental handpiece with intended use of being a Surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used.	Karam 45 and Dexor 45 are air-powered high speed dental handpieces with intended use of being a surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used.
Principle of operation	Through the tube and the coupling connected to a dental unit, the air-powered handpiece receives the air for operating the high speed turbine, the cooling water for cutting treatment through one port and light for illumination the operation area.	Through the tube and the coupling connected to a dental unit, the air-powered handpiece receives the air for operating the high speed turbine, the cooling water for cutting treatment through one port and light for illumination the operation area.	Through the tube and the coupling connected to a dental unit, the air-powered handpiece receives the air for operating the high speed turbine, the cooling water for cutting treatment through one port.
Water ports	One	Three	One
Fiber optics	With built-in light system	With and without built-in light system	without built-in light system
Dimensions	Head size-Height: 14,6 mm Head size-Diameter: 12,5 mm	Head size-Height: 13,6 mm Head size-Diameter: 11,2 mm	Head size-Height: 13,6 mm Head size-Diameter: 11,2 mm
Type of chuck	Push Button	Same	Same
Power (approx.)	19 watts	21 watts	16 watts
Coupling Dimensions	Length with coupling: Approx. 121 mm	Information not available	Information not available
Chemical composition of the patient-contacting portions of the device	Round Copper 17,463 (2.0375 / CuZn36Pb3) and Cr-N/Cr Coating Round Steel 12,7 (1.4305_303 / X8CrNiS18-9) and Cr Coating Ecobrass 40 (C6930/ CuZn21Si3P) Round Steel 12,7 (1.4305_303 / X8CrNiS18-	Information not available	Stainless steel, aluminum alloy, copper alloy, chrome plating, nickel plating, elastomer

	9) and Cr Coating (See details in Section XVI)		
Chemical composition of the water tube	German Silver1,2 (2.0730 / CuNi12Zn24) with Cr coating (See details in Section XVI)	Stainless steel	Information not available
Light Intensity	Approx. 25,000 LUX	Same	without light system
Bur retention force	Up to 24 Ncm	Same	Same
Operating Pressure	40 ± 1.45 psi recommended	32 to 44 psi recommended	29 - 36 psi recommended
Idling Speed	380,000 - 420,000 rpm	380,000 – 450,000 rpm	380,000 - 450,000 rpm
Head angle	45-degree	Same	Same
Compliance to Standards	Complies with ISO 14457 and ISO 9168	Complies with ISO 7785-1 and ISO 9168	Complies with ISO 7785-1 and ISO 9168
Lubricant	KaVo Spray Henry Schein Spray & Clean	PANA SPRAY Plus PANA SPRAY	Karam Spray

Non-Clinical Test Data:

- Performance tests according to the international standards ISO 14457 First edition 2012-09-15 - Dentistry – Handpieces and Motors for proposed dental air-driven handpieces has been conducted to determine the conformance to the state of the art. Biocompatibility per ISO 10993 and sterilization validation have been completed which demonstrate that the proposed devices are substantially equivalent to the predicate devices.
- ISO 9168 Third edition 2009-07-15 - Dentistry - Hose connectors for air driven dental handpieces

Clinical Test Data:

Clinical testing was determined to be not required for this product.

Conclusion:

Based upon the tests according to the international standards listed above for dental air-driven handpieces, the biocompatibility and sterilization studies and the similar technological and performance characteristics as compared to the predicate devices, the performance of the Maxima PRO 45L is deemed perform as well as the predicate devices.